EXHIBIT 20

All tests marked * in this technical report were subcontracted to test facilities accredited to ISO/IEC 17
by CNAS.

Detailed results are included on the following page(s)

Global Tooling Service S.R.O
SATRA Reference: CHT0300498 /2030
Date: 4 August 2020 (Page 2 of 9)
Signed: Technolog
China Tes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrati
10903 New Hampshire Ave
Document Control Center -
Silver Spring, MD 20993-0

March 9, 2016

Zhonghong Pulin Medical Products Co., Ltd.
c/o Mr. Chu Xiaoan
Room 1606 Bldg. 1, Jianxiang Yuan No. 209
Bei Si Huan Zhong Road, Haidian District
Beijing 100083
CHINA

Re: K152712
Trade/Device Name: Nitrile Powder Free Patient Examination Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: January 28, 2016
Received: February 1, 2016

Dear Mr. Xiaoan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indicatio for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or devices that have been reclassified in accordance with the provisions of the Federal Food, Dru and Cosmetic Act (Act) that do not require approval of a premarket approval application (PM You may, therefore, market the device, subject to the general controls provisions of the Act. T general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading

If your device is classified (see above) into either class II (Special Controls) or class III (PMA it may be subject to additional controls. Existing major regulations affecting your device can b found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not me that FDA has made a determination that your device complies with other requirements of the or any Federal statutes and regulations administered by other Federal agencies. You must com with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth i